



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2019-0094]

**Recommendations for Hepatitis C Screening among Adults-
2019; Request for Comment**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice and request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services announces the opening of a public docket to obtain public comment on proposed new recommendations for hepatitis C virus (HCV) infection screening for adults, including pregnant women. The new recommendations are intended for U.S. healthcare providers and will include supporting scientific evidence of the effectiveness and economic value

of screening to diagnose current HCV infection among adults and pregnant women in the United States.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0094 by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of Viral Hepatitis, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop U12-3, Atlanta, GA 30329, Attn: Docket No. CDC-2019-0094.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: CDR Sarah Schillie, MD,
MPH, MBA, Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Mailstop U12-3, Atlanta, GA
30329. Email: DVHpolicy@cdc.gov. Telephone: (404) 639-
8000.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. In addition, CDC invites comments specifically on the following questions:

- Based on the evidence presented in the full recommendations document (see the Supporting and Related Materials tab in the docket), do you agree with CDC's proposed recommendations for HCV infection screening? If not, please state the reason why and, if available, provide additional evidence for consideration.
- Are CDC's recommendations (see Supporting and Related Materials) clear as written? If not, what changes do you propose to make them clearer?
- If implemented as proposed, do you believe these

recommendations would result in a reduction in HCV infections and associated health and financial consequences in the United States? If not, please provide an explanation.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted in preparation of the final recommendation and may revise as appropriate.

Background and Brief Description

Hepatitis C Virus (HCV) infection is the most commonly

reported blood-borne infection in the United States (CDC Viral Hepatitis Surveillance, 2019; Rosenberg et al, 2018), and during 2013-2016 there were an estimated 2.4 million people in the nation (or 1.0% of the U.S. population) living with hepatitis C (Hofmeister et al, 2019). Percutaneous exposure (e.g., injection drug use, blood transfusion) is the most efficient mode of HCV transmission, and injection drug use is the primary risk factor for infection (CDC Viral Hepatitis Surveillance, 2017). National surveillance data reveal an increase in reported cases of acute HCV infection every year from 2009 through 2017, the most recent year for which there is data. The highest rates of acute cases are among persons aged 20-39 years (CDC Viral Hepatitis Surveillance, 2017). As new HCV infections have risen among reproductive aged adults, rates of HCV infection nearly doubled from 2009-2014 among women with live births (Patrick et al, 2017). In 2015, 0.38% of live births were delivered by HCV-infected women (Schillie et al, 2018). Given the current rate and trends of HCV infections, CDC has decided to augment the current guidelines to address the rise in HCV infections among adults in the U.S.

As described in the recommendation document found in the Supporting and Related Materials tab of the docket,

these recommendations augment previously published CDC recommendations for the identification of hepatitis C in the United States (Smith et al, 2012; CDC HCV Recommendations, 1998).

Dated: October 23, 2019.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.

[FR Doc. 2019-23521 Filed: 10/25/2019 8:45 am; Publication Date: 10/28/2019]